REMARKS/ARGUMENT

Regarding the Requirement for Election/Restriction:

The Examiner's attention is respectfully directed to what appear to be several inconsistencies in the prosecution, particularly as related to the Requirements for Election/Restriction and the Responses thereto. The application was filed on February 5, 2002 including 68 claims. In a Preliminary Amendment filed July 2, 2002, claims 1, 7, 28, 35, 41, 63, 67, and 68 were amended, and claims 69-76 were added. Claims 69, 70, and 73-76 are method claims and claims 71 and 72 are apparatus claims.

In the original Restriction Requirement, mailed October 1, 2004, only claims 1-68 were referred to. In the Response mailed December 20, 2004, this omission was not referred to, but method claims 1-34 were elected, along with Species C of Figure 6a.

In a second Election Requirement, mailed March 24, 2005, there was again no reference to claims 69-76. Moreover, in acknowledging applicant's Response, the Examiner noted election of Group I which she identified as encompassing claims 1-33, rather than claims 1-34. Further, this second Election Requirement directed election of a single species from each of what the Examiner identified as Groups A and B. Group A includes species she identified as Species A-F, Group B was identified as including Species AA-VV. Some of the latter were referred to as pertaining to methods and others to apparatus.

Responding according to applicant's understanding of the intended meaning, claims 1-10 and 35-44 were elected, together with Species F from Group A and Species AA from Group B. It was further noted that all claims read on Species AA.

In the outstanding Office Action on the merits, despite her express direction to applicant to elect one species from each of the groups, it appears that the Examiner has ignored the election, and examined only claims 1-10. The legal and logical basis for this decision by the Examiner is not understood.

Moreover, as of the date of the outstanding Office Action, approximately three and one-half years after the application was filed, and about three years after claims 69-76 were added to the application, they still have not been addressed in any way by the Examiner. As to these, applicant

considers claims 69, 70, and 71 to be within the scope of the election, and requests examination of these claims along with claims 1-10 and 35-44.

In view of the foregoing, clarification, and reconsideration by the Examiner of her treatment of the Election Requirements and applicant's Response thereto, are respectfully requested.

Regarding the Claims in General:

Claims 1-75 are now pending, as explained above. Claims 1, 7, 8, 9, and 35-43 have been amended to address the outstanding rejections (it being applicant's contention that he is entitled to examination of claims 35-44 and 69-71, as well as claims 1-10).

Regarding the Prior Art Rejections:

In the outstanding Office Action, claims 1-10 were rejected under 35 U.S.C. §102(e) as being anticipated by Magers U.S. Patent 6,830,581 (Magers '581), or Dobak, III et al. U.S. Published Application 2001/0011184 A1 (Dobak), or Magers et al. U.S. Published Application 2003/0088299 (Magers '299). Reconsideration and withdrawal of the rejections are accordingly requested, in view of the amendments herein.

As amended, claim 1 is directed to a method for hypothermia, involving the steps of:

> providing a container with an infusion solution having a first temperature and a venous infusion catheter connected to an outlet of said container, said venous infusion catheter having an infusion solution lumen;
>
> percutaneously inserting a distal end of said venous infusion catheter into a peripheral vein;
>
> cooling the infusion solution to a second temperature lower than said first temperature; and
>
> infusing said cooled infusion solution into said vein via the infusion solution lumen of said venous infusion catheter shortly after said cooling, to enable the cooled infusion solution to cool the blood while avoiding formation of air bubbles when supplied to said vein.

With due respect, there does not appear to be any basis for the Examiner's assertion that this claim is anticipated any of the references. In particular, none of the three references teaches

the infusion of a solution *into* a vein. To the contrary, the solution is always maintained inside a heat transfer element. Thus, the three references fail to disclose, teach, or suggest an important feature of claim 1, and cannot anticipate the claim.

Claim 35, of which applicant regards himself entitled to examination as explained above, is directed to hypothermia equipment comprising:

> a container with an infusion solution having a first temperature and a venous infusion catheter being connectable to an outlet of said container, said venous infusion catheter having an infusion solution lumen;
>
> said venous infusion catheter having a distal end devised to be percutaneously inserted into a peripheral vein;
>
> a cooling device being configured for cooling the infusion solution to a second temperature lower than said first temperature; and
>
> an infusing device being configured to infuse said cooled infusion solution into said vein via the infusion solution lumen of said venous infusion catheter shortly after said cooling, to enable the cooled infusion solution to cool the blood while avoiding formation of air bubbles when supplied to said vein.

This claim is substantively comparable to claim 1, but in apparatus form, and is likewise not anticipated by any of the references since there is no disclosure, teaching or suggestion of venous infusion.

Other important features of the invention as recited in claims 1 and 35 are also not disclosed, taught or suggested by the references. For example, Dobak teaches at paragraph 0012 the perfusion of a cold solution, which process is commonly used to protect the heart during heart surgery and is referred to as cardioplegia. However, the present invention relates to infusion of a cooled solution into a peripheral vein.

Moreover, according to claims 1 and 35 as amended, the cooled infusion solution is infused into the vein shortly after the cooling. (The Examiner is respectfully referred to paragraph 0175 of the present patent application where the relevance of this feature is explained.) When the infusion solution is cooled down to the second temperature, which may be 4 degrees Celsius, the solubility of gases included in the air increases. If the infusion solution is maintained at such a low temperature

and exposed to air for a period of time, gases, such as oxygen and nitrogen, will dissolve in the infusion solution. When the infusion solution is subsequently heated to near 37 degrees Celsius during mixing with the blood in the vein, the solubility of the dissolved gases will decrease and the gases may be released in the blood in the vein, possibly resulting in air bubbles in the blood, which may be undesirable, although an amount of small air bubbles can be tolerated. In order to at least partly remedy such formation of air bubbles inside the vein, the infusion solution is introduced shortly after cooling, whereby substantially no gases have had time to dissolve in the infusion solution.

The references do mention removal of air from the cooling medium, see, for example, Magers '581, column 67, lines 47-65, where it is stated that "The air purging mechanism is used to remove air from the lines and lumens of the system... The removal or purging of air from the system is important for maximizing the pressure in the system, maximizing heat transfer at the heat transfer element, and preventing air from possibly entering the blood stream of the patient caused by a break or leak in the catheter." However, Magers only teaches the removal (purge) of air which has already escaped inside the lines and lumens of the system and is free therein. Magers does not teach how to avoid the *formation* of air bubbles when the cooled infusion solution increases its temperature inside the vein. Needless to say, it would not be possible to purge the vein! The feature defined in claims 1 and 35 solve this problem.

Claims 2-9 and 36-44 are respectively dependent, directly or indirectly, on allowable claims 1 and 35, and are therefore also allowable for the reasons stated above. In addition, these claims recite features which, in combination with the features of their respective parent claims are neither taught nor suggested in any of the applied references.

For example, claim 6 defines that the infusion solution is a hypotonic saline solution, and claim 8 defines that the infusion solution has a low osmolarity. These features are not disclosed in any of the references.

Likewise, claim 9 defines a further feature, in which the infusion solution is maintained in an air-sealed container at a temperature in the range of 37 degrees Celsius before cooling, so that the dissolved gases are within a range so that air bubbles cannot substantially be formed in the vein.

As noted above, applicant considers that claims 69 and 70, which are both dependent on claim 1, should be examined along with their parent claim. Similarly, claim 71 which is dependent on claim

35, should also be examined with its parent claim. These claims are also patentable for the reasons stated above in reference to claims 1 and 35.

In view of the foregoing, favorable reconsideration of the requirement for election and restriction, and of the rejections of this application are respectfully solicited.

I hereby certify that this correspondence is being transmitted by Facsimile to (571) 273-8300 addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date indicated below.

Lawrence A Hoffman
Name of applicant, assignee or Registered Representative

Signature

January 25, 2006
Date of Signature

LAH:lac

Respectfully submitted,

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